

Appl. No. : 08/779,767
Filed : January 7, 1997

making a pharmaceutical compound classified in class 424, subclass 182.1. The claims of Group IV (39-48) are indicated as being drawn to methods of administering an immunomodulating compound and classified in class 424, subclass 182.1. Group V (claims 49-60), held directed to polynucleotides and transformed cells comprising the same, is classified in class 536, subclass 23.4. Finally, Group VI (claims 61-65) is held to be drawn to *in vitro* methods of endocytic presentation classified in class 435, subclass 7.1. The Official Action maintains that Groups I to VI constitute separate and distinct inventions that have acquired separate status in the art as shown by their different classification.

By way of response to the instant restriction requirement, Applicant provisionally elects, with traverse, to prosecute the claims of Group I. Group I, as set forth by the Examiner in the subject Official Action, comprises claims 1-11 and 22-29 which are drawn to compounds and compositions comprising fusions of a Fc receptor ligand and immunosuppressive factor. Notwithstanding this election, Applicant expressly reserves the right to rejoin withdrawn process claims for making and using the compounds and compositions of Group I upon notification of allowable subject matter in the elected invention.¹ Moreover, Applicant respectfully submits that compelling reasons, set forth below following the required election of species, merit immediate withdrawal of the restriction requirement and rejoinder of all the claims for the purposes of examination.

As alluded to above, Applicant is also required to elect a single disclosed species of protein for prosecution on the merits. Specifically, the subject Official Action requires Applicant to select either myelin basic protein or proteolytic protein for the purposes of examination. Upon further review of the application, it is believed that the intended election comprises selecting either myelin basic protein or proteolipid protein for examination. That is, as set forth on page 9, line 8 of the instant application, both myelin basic protein and proteolipid protein comprise myelin antigens that provide for the development of immunomodulating agents which may be useful in the present invention. Conversely, Applicant could not readily find any

¹ In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995).
In re Brouwer, **F.3d**, 37 USPQ2d 1663 (Fed. Cir. 1996).

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mention of a proteolytic protein that could be used in the development of immunomodulating agents. If this assumption is incorrect, clarification is respectfully requested.

With regard to the specific election requirement, Applicant hereby elects the species of "proteolipid protein" upon which claims 4, 14, 24, 32 and 41 are readable. Claims 1-3, 6-13, 16-23, 26-31, 34-40 and 43-65 are generic to the elected species.

This election is made without traverse to the extent that it is understood that (a) the requirement will be withdrawn upon finding of an allowable genus; and (b) any species withdrawn from consideration will be transferred to the elected subject matter unless it is found to be patentably distinct from the elected or allowed claims.

In another matter, Applicant notes that Group IV was not selected for prosecution on the merits. As such, no election of species has been made at the present time with respect to the various autoimmune disorders that may be treated in accordance with the present invention.

Turning now to the traversal of the instant restriction requirement, it is well established that a showing must be made that failure to separate the inventions will result in a serious burden being placed on the Patent Office. In the instant case, Applicant respectfully submits that such a showing has not been made with regard to each of the enumerated inventions.

More particularly, Applicant believes a search of the prior art with respect to the claimed subject matter would not substantially increase the burden on the Patent Office. To the contrary, it is submitted that a search of the individual Groups, as identified by the Examiner, will clearly be coextensive with respect to one or more of the inventions. That is, any search directed to immunomodulating agents comprising a fusion of an Fc receptor ligand and an immunosuppressive factor will most likely encompass methods of making such agents as well as methods of their use. Similarly, any search covering the claimed compositions will likely include subject matter pertaining to methods of their formation comprising recombinant polynucleotides and their expression in transformed cells. Evidence for the coextensive nature of such searches is provided by the overlapping classification of the individual groups in the instant Official Action. Accordingly, as it is believed that the burden imposed on the PTO does

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not rise to the requisite level, Applicants urge that the restriction requirement be withdrawn and all the pending claims rejoined for the purposes of examination.

No additional fees are seen as being necessary in connection with this response. However, the Assistant Commissioner is authorized to charge any fees or credit any overpayment to our Deposit Account No. 01-1008.

Respectfully submitted,

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